APOTEX CORP.

616 HEATHROW DRIVE • LINCOLNSHIRE • ILLINOIS 60069 • TEL: (847) 821-8005 • FAX: (847) 821-1001

July 16, 2004

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

Apotex Corp. submits this petition under section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act. We seek approval to file an Abbreviated New Drug Application (ANDA) for Adenosine Injection, USP 3 mg/mL with 6 mL and 10 mL fill volumes (total drug content 18 mg/6 mL and 30 mg/10 mL respectively).

Adenosine is currently marketed as a sterile injection product, Adenocard® IV (Adenosine Injection) by Fujisawa Healthcare, Inc. in three configurations: 3 mg/mL, 2 mL vials, and 2 mL and 4 mL syringes.

Draft copy of the package insert for the proposed product, Adenosine Injection, USP is included (Appendix B) along with a copy of the package insert for the reference listed product, Adenocard® IV (Adenosine Injection) (Appendix A).

A. Action Requested

The petitioner requests the Commissioner to declare Adenosine Injection, USP 3 mg/mL in 6 mL and 10 mL fill volumes suitable for consideration in an abbreviated new drug application.

B. Statement of Grounds

Fujisawa Healthcare, Inc. currently markets Adenocard® IV (Adenosine Injection) in the configurations as stated above. Apotex Corp. would like to submit an ANDA for Adenosine Injection, USP 3 mg/mL in 6 mL and 10 mL fill volumes as supported by the following:

1. The strength of Apotex Corp.'s proposed product is identical to that of Adenocard® IV (Adenosine Injection) when the directions listed on the product insert (see Appendix A) are followed.

   The formulation of Adenocard® IV (Adenosine Injection) and Apotex Corp.'s Adenosine Injection, USP are compared in the following table:

Product	**Adenocard® IV (Adenosine Injection)**	**Apotex Corp.'s Adenosine Injection, USP**
Adenosine, USP	3 mg/mL	3 mg/mL
Sodium Chloride, USP	9 mg/mL	9 mg/mL
Water for Injection, USP	q.s. to 1 mL	q.s. to 1 mL

   The above table shows that the drug content per mL of Apotex Corp.'s proposed product is identical to that of Adenocard® IV (Adenosine Injection).

2. As the active ingredient is identical to the approved product on the market, there is no obvious difference in the safety and efficacy between Adenosine Injection, USP and Adenocard® IV (Adenosine Injection).

3. The dosage and administration of the proposed drug product is the same as that for the listed drug product, as recommended in the DOSAGE AND ADMINISTRATION Section of the proposed package insert (Appendix B).

   Since there is no alteration to the active ingredient, route of administration or dosage from, the required change in total drug content per container is the only reason for this petition.

The rationale for developing such a product is based upon the advantages that a multi-dose vial offers over the currently marketed product fills from Fujisawa Healthcare Inc. These include the following:

1. Apotex Corp's proposed presentations, 6 mL and 10 mL fill sizes, contain the amount prescribed for *Adult Patients* in Adenocard's package insert, as follows:

Initial dose: 6 mg given as a rapid intravenous bolus (administered over a 1-2 second period).
Repeat administration: If the first dose does not result in elimination of the supraventricular tachycardia within 1-2 minutes, 12 mg should be given as a rapid intravenous bolus. This 12 mg dose may be repeated a second time if required.

The 6 mL fill size will contain a quantity sufficient to dose an adult patient through the 2nd intravenous bolus dose (total of 18 mg on a 6 mL). The 10 mL fill size, would contain a quantity sufficient to dose the adult patient if a third intravenous bolus dose was required (30 mg on 10 mL).

2. A single multi dose vial is more cost-efficient than 2 mL vials, and 2 mL and 4 mL syringes.
3. Vials are also space-efficient and produce less waste than single-use syringes.

Accordingly, Apotex Corp. believes that the facts presented in this Citizen Petition for Adenosine Injection, USP 3 mg/mL in 6 mL and 10 mL fill volumes multi-dose vials deem our product suitable for an abbreviated new drug application.

C. Environmental Impact

An Environmental Impact Analysis Report for the action requested (i.e., the determination that Adenosine Injection, USP 3 mg/mL in 6 mL and 10 mL fill volumes is suitable for ANDA status) is not required as cited under 21 CFR 25.24(c)(1).

D. Economic Impact

Information regarding economic impact will be made upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petitioner.

Respectfully Submitted,

By: Marcy Macdonald

Marcy Macdonald
Director, Regulatory Affairs
Apotex Corp.
616 Heathrow Drive
Lincolnshire, IL 60069
Telephone: (847) 279 7740
Facsimile: (847) 353 2982